SENATE BILL No. 1081

Introduced by Committee on Health and Human Services (Senators Ortiz (Chair), Alarcon, Battin, Chesbro, Escutia, Figueroa, Florez, Kuehl, Romero, Vasconcellos, and Vincent)

April 3, 2003

An act to amend Sections 1603.1, 1603.2, 1603.3, and 1603.4 of the Health and Safety Code, relating to human blood.

LEGISLATIVE COUNSEL'S DIGEST

SB 1081, as introduced, Committee on Health and Human Services. Human blood.

(1) Existing law requires any person engaged in the production of human whole blood or human whole blood derivatives to be licensed by the State Department of Health Services. Existing law also contains various provisions relating to consent to, and the disclosure of results of, testing for antibodies to the human immunodeficiency virus (HIV), the probable causative agent of acquired immune deficiency syndrome (AIDS), and the presence of viral hepatitis.

Existing law requires each blood bank or plasma center to notify the department and county health officer, as specified, if the presence of viral hepatitis, or the antigen thereof, is found in the blood tested, and in these cases, to provide additional information, as prescribed. Existing law also requires a physician to report to the department and the county health officer certain information regarding all carriers of viral hepatitis under his or her treatment, and requires a hospital to report to the department and to the county health officer certain information regarding all confirmed cases of AIDS carriers and all carriers of viral hepatitis hospitalized for treatment of viral hepatitis or AIDS.

This bill would delete the requirement that these notifications and reports be made to the department.

(2) Existing law requires the county health officer to investigate all transfusion-associated hepatitis cases and transfusion-associated AIDS cases and to trace the sources of human whole blood that was transfused.

This bill would instead require the county health officer, upon receipt of a report concerning any transfusion-associated hepatitis or transfusion-associated AIDS case, to identify which blood bank or plasma center is the source of the tainted blood and to report this fact to the blood bank or plasma center that issued the blood. It would require the blood bank or plasma center to undertake an investigation to determine the donor source of the tainted blood.

(3) Existing law requires the department to compile a list of carrier donors, possible carrier donors, and carriers of viral hepatitis and persons who test reactive for HIV and to distribute that list, known as the Donor Deferral Register, to blood banks and plasma centers, as specified. Existing law requires blood banks and plasma centers, after a confirmation test, to report information to the department to be included in the Donor Deferral Register, as specified. Existing law also requires the department, if possible, to contact carrier donors to inform them that they may be carriers of viral hepatitis and should not make blood donations, and to suggest appropriate treatment alternatives.

This bill would delete these requirements.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

The people of the State of California do enact as follows:

SECTION 1. Section 1603.1 of the Health and Safety Code is amended to read:

1603.1. (a) Except as provided in this subdivision, no blood or blood components shall be used in vivo for humans in this state, unless the blood or blood components have been tested and found nonreactive for HIV or the blood or blood components are used for research or vaccination programs pursuant to an informed consent.

Additional exceptions to the requirement of this subdivision are as follows:

(1) Frozen red blood cells of a rare type, as determined by the blood bank or plasma center, collected prior to the effective date of this paragraph, for which no specimen is available.

(2) Inventories of blood and blood components collected prior to 60 days after the effective date of this paragraph or the date of licensing of a test by the Federal Drug Administration to determine exposure to the antibodies to the probable causative agent of AIDS, whichever is later.

(3) Blood or blood products released for transfusion in emergency circumstances, as determined by the ~~state~~ department.

(4) Blood used for autologous purposes.

(b) Blood banks and plasma centers shall make laboratory tests of all human whole blood and plasma received to detect the presence of viral hepatitis and HIV in the manner specified in Section 1603.3. If the blood bank or plasma center finds the presence of viral hepatitis, or an antigen thereof, in the blood tested, it shall report that finding, the date of the human whole blood donation, the name, address, and social security number of the person who donated the blood, and the name and address of the blood bank which received the human whole blood from the person and any additional information required by the department, to ~~the department and~~ the county health officer within 72 hours of the confirmation of the presence of viral hepatitis, or an antigen thereof, in the blood tested.

(c) As soon as practicable following diagnosis, a physician shall report to ~~the department and~~ the county health officer the name, date of birth, address, and social security number of all carriers of viral hepatitis under his or her treatment, the type of viral hepatitis contracted if known, and any additional information required by the department and shall report immediately all transfusion-associated hepatitis and transfusion-associated AIDS cases to the county health officer for investigation.

(d) As soon as practicable following hospitalization, a hospital shall report ~~to the department and~~ to the county health officer the name, date of birth, address, and social security number of all confirmed cases of AIDS carriers, as determined by a person responsible for the care and treatment of a person with AIDS, and all carriers of viral hepatitis hospitalized for treatment of viral hepatitis or AIDS, the name of the hospital, the date of hospitalization, the type of viral hepatitis contracted if known, and any additional information required by the department and shall report immediately all transfusion-associated hepatitis and all confirmed transfusion-associated AIDS cases, as determined by a

person responsible for the care and treatment of a person with AIDS, to the county health officer for investigation.

(e) ~~The county health officer shall investigate all transfusion-associated hepatitis cases and transfusion-associated AIDS cases and shall, if possible, trace the sources of human whole blood which was transfused. The county health officer shall report to the department within 72 hours following an investigation the name, date of birth, address, and social security number of carrier donors, possible carrier donors and carriers of viral hepatitis and any additional information required by the department~~ *Upon receipt of a report concerning any transfusion-associated hepatitis or transfusion-associated AIDS cases, the county health officer shall identify which blood bank or plasma center is the source of the tainted blood and shall report this fact to the blood bank or plasma center that issued the blood. The blood bank or plasma center shall undertake an investigation to determine the donor source of the tainted blood.*

~~(f) The department shall compile two times each month a list of carrier donors, possible carrier donors, and carriers of viral hepatitis and persons who test reactive for HIV and shall distribute the list to blood banks and plasma centers two times each month. The list shall include the name, date of birth, address, and social security number of people who are carrier donors, possible carrier donors and carriers of viral hepatitis and persons who test reactive for HIV, and confirmed cases of AIDS, as determined by a person responsible for the care and treatment of a person with AIDS, the date of the human whole blood donation if applicable, the name and address of the blood bank who received the human whole blood donation if applicable, and any other information which the department deems necessary to protect the public health and safety. This list shall be known as the Donor Deferral Register and shall include names of individuals who are indefinitely deferred from blood donations without identifying the reasons for the deferral. The state department may develop guidelines governing the instances when a person is to be removed from the register. These guidelines may include, but shall not be limited to nor be required to include, death of an identified donor or the licensure by the Federal Food and Drug Administration of a new, confirmatory test for AIDS which would allow the state department to more accurately determine if a person should be~~

~~kept on the registry due to any threat to the state's blood supply that the prospective donor may represent.~~

~~(g) The department shall, if possible, contact carrier donors to inform them that they may be carriers of viral hepatitis and should not make blood donations, and shall suggest appropriate treatment alternatives.~~

(f) County health or ~~state~~ department officials shall contact all persons who have confirmed cases of AIDS, as determined by a person responsible for the care and treatment of the person with AIDS, to suggest appropriate treatment alternatives and for the purposes of epidemiological studies and followup.

~~(h)~~

(g) The department may adopt regulations governing the procedures in this section as it deems necessary to protect the public health and safety.

~~(i)~~

(h) ''Plasma center,'' as used in this chapter, means any place where the process of plasmapheresis is conducted, as defined in Section 1025 of Title 17 of the California Code of Regulations and includes a place where leukopheresis or platelet pheresis, or both, is conducted.

~~(j)~~

(i) ''AIDS,'' as used in this chapter, means acquired immune deficiency syndrome.

~~(k)~~

(j) ''Blood components,'' as used in this chapter, means preparations separated from single units of whole blood or prepared for hemapheresis and intended for use as final products for transfusions.

~~*(l)*~~

(k) The department or a county health officer may disclose to a blood bank, on a confidential basis, ~~any information reported pursuant to subdivision (b), (c), or (d). This information shall be used by the blood bank solely to determine~~ whether blood previously transfused may have been donated by a person infected with HIV, in order to implement the blood bank's program to notify a recipient of blood ~~which~~ *that* might have transmitted HIV and ~~which~~ *that* was donated prior to implementation of testing procedures for the presence of antibodies to the probable causative agent of HIV. The blood bank ~~shall~~ *may* not disclose information

that would identify a donor to which this subdivision applies and shall destroy information communicated to it as authorized by this subdivision immediately after reviewing its records as necessary to implement this program.

SEC. 2. Section 1603.2 of the Health and Safety Code is amended to read:

1603.2. (a) ~~No blood bank shall, for any reason, receive human whole blood from a person who is listed as a carrier donor or a carrier of viral hepatitis on a list distributed by the department.~~

~~(b)~~ Each blood bank shall require as identification either a photographic driver's license or other photographic identification which is issued by the Department of Motor Vehicles, pursuant to Division 6 (commencing with Section 12500) of the Vehicle Code, from all donors of human whole blood who receive payment in return for the donation of ~~such~~ *that* blood.

~~For~~

(b) For the purposes of this section, ''payment'' means the transfer by a blood bank to any person of money or any other valuable consideration ~~which~~ *that* can be converted to money by the recipient, except that payment shall not include any of the following:

(1) Cancellation or refund of the nonreplacement fees or related blood transfusion ~~charges;~~ *charges.*

(2) Blood assurance benefits to a person as a result of a blood donation to a donor club or blood assurance ~~program; or~~ *program.*

(3) Time away from employment granted by an employer to an employee in order to donate blood.

SEC. 3. Section 1603.3 of the Health and Safety Code is amended to read:

1603.3. (a) Prior to a donation of blood or blood components, each donor shall be notified in writing of, and shall have signed a written statement confirming the notification of, all of the following:

(1) That the blood or blood components shall be tested for evidence of antibodies to the probable causative agent of acquired immune deficiency syndrome.

(2) ~~That donors found to have serologic evidence of the antibodies shall be placed on a confidential statewide Blood Donor Deferral Register without a listing of the reason for being included on the register.~~

~~(3)~~ That the donor shall be notified of the test results in accordance with the requirements described in subdivision (c).

~~(4)~~

(3) That the donor blood or blood component that is found to have the antibodies shall not be used for transfusion.

~~(5)~~

(4) That blood or blood components shall not be donated for transfusion purposes by a person if the person has reason to believe that he or she has been exposed to acquired immune deficiency syndrome.

~~(6)~~

(5) That the donor is required to complete a health screening questionnaire to assist in the determination as to whether he or she has been exposed to acquired immune deficiency syndrome.

(b) A blood bank or plasma center shall incorporate voluntary means of self-deferral for donors. The means of self-deferral may include, but are not limited to, a form with checkoff boxes specifying that the blood donated is for research or test purposes only and a telephone callback system for donors to use in order to inform the blood bank that blood donated should not be used for transfusion. The blood bank or plasma center shall inform the donor, in a manner that is understandable to the donor, that the self-deferral process is available and should be used if the donor has reason to believe that he or she is infected with the human immunodeficiency virus. The blood bank or plasma center shall also inform the donor that it is a felony pursuant to Section 1621.5 to donate blood if the donor knows that he or she has a diagnosis of AIDS or knows that he or she has tested reactive to the etiologic agent of AIDS or to antibodies to that agent.

(c) Blood or blood products from any donor initially found to have serologic evidence of antibodies to the probable causative agent of AIDS shall be retested for confirmation. Only if a further test confirms the conclusion of the earlier test shall the donor be notified of a reactive result by the blood bank or plasma center.

The ~~state~~ department shall develop permissive guidelines for blood banks and plasma centers on the method ~~or methods~~ to be used to notify a donor of a test result. ~~Each blood bank or plasma center shall, upon positive confirmation using the best available and reasonable techniques, provide the information to the state department for inclusion in the Donor Deferral Register. Blood~~

~~banks and plasma centers shall provide the information on donations testing reactive for the antibodies to the probable causative agent of AIDS and carrier donors of viral hepatitis to the department on a single list in the same manner without specification of the reason the donor appears on the list.~~

(d) ~~The Blood Donor Deferral Register, as described in subdivision (e) of Section 1603.1, shall include names of individuals who are deferred from blood donations without identifying the reasons for deferral.~~

~~(e)~~ Each blood bank or plasma center operating in California shall prominently display at each of its collection sites a notice that provides the addresses and telephone numbers of sites, within the proximate area of the blood bank or plasma center, where tests provided pursuant to Chapter 3 (commencing with Section 120885) of Part 4 of Division 105 may be administered without charge.

~~(f)~~

(e) The~~ state~~ department may promulgate any additional regulations it deems necessary to enhance the safety of donated blood and plasma. The~~ state~~ department may also promulgate regulations it deems necessary to safeguard the consistency and accuracy of HIV test results by requiring any confirmatory testing the~~ state~~ department deems appropriate for the particular types of HIV tests that have yielded ''reactive,'' ''positive,'' ''indeterminate,'' or other similarly labeled results.

~~(g)~~

(f) Notwithstanding any other provision of law, no civil liability or criminal sanction shall be imposed for disclosure of test results to a public health officer when the disclosure is necessary to locate and notify a blood donor of a reactive result if reasonable efforts by the blood bank or plasma center to locate the donor have failed. Upon completion of the public health officer's efforts to locate and notify a blood donor of a reactive result, all records obtained from the blood bank pursuant to this subdivision, or maintained pursuant to this subdivision, including, but not limited to, any individual identifying information or test results, shall be expunged by the public health officer.

SEC. 4. Section 1603.4 of the Health and Safety Code is amended to read:

1603.4. (a) Notwithstanding Chapter 7 (commencing with Section 120975) of Part 4 of Division 105, ~~as added by Chapter 22 of the Statutes of 1985,~~ or any other provision of law, no public entity or any private blood bank or plasma center shall be liable for an inadvertent, accidental, or otherwise unintentional disclosure of the results of an HIV test ~~or information in the Donor Referral Register~~.

As used in this section, ''public entity'' includes, but is not limited to, any publicly owned or operated blood bank or plasma center and the ~~state~~ department.

(b) Neither the ~~state~~ department nor any blood bank or plasma center, including a blood bank or plasma center owned or operated by a public entity, shall be held liable for any damage resulting from the notification of test results, as set forth in paragraph ~~(3)~~ *(2)* of subdivision (a) of, or in subdivision (c) of, Section 1603.3.

O